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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,277	03/29/2002	Ana Lucia Teles Rabello	3673-15	3261

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[REDACTED] EXAMINER

JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,277	RABELLO ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 October 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) 1-8 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 29 March 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1201.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: Notice to Comply

DETAILED ACTION

1. This application is a 371 of PCT/BR01/00035, filed April 4, 2001. It is noted that the International Search for PCT/BR01/00035 has been received and considered.

Specification

2. The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a) and (a)(2). However, the specification fails to comply with one or more of the requirements of 37 CFR § 1.821 through 1.825 because the specification recite sequences that lack description by the appropriate sequence identifier set forth in the "Sequence Listing" as required by 37 CFR § 1.821(d). See, for example, Figure 1. Appropriate corrections for compliance are required. Specifically, Applicant must either file substitute a substitute Figure that recites the appropriate sequence identifier, or amend the brief description of the figures so as to set forth said sequence identifier. See MPEP 2422.02. As Applicants' drawings have been accepted, it is suggested that the description of Figure 1 be amended.

3. The disclosure is objected to because of the following informalities: the specification employs the notation "ID SEQ n." rather than the accepted, standard identifier "SEQ ID NO:". Appropriate correction is required.

4. The use of the trademark GLASSMAX™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

5. The abstract of the disclosure is objected to because it is not a single paragraph, and because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Objections

6. Claims 1-8 are objected to because of the following informalities: the claims employ the notation "ID SEQ n." rather than the accepted, standard identifier "SEQ ID NO:". Appropriate correction is required.

7. Claims 1-3 are objected to because of the following informalities: claim 1 includes a period at the end of step (c). This objection could be overcome by amending the claim to recite ";" and" in lieu of the period. Appropriate correction is required.

New Matter

8. The paper and computer readable forms of the Sequence Listing filed in response to the Notice of April 16, 2002 are objected to under 35 U.S.C. 132 because they introduce new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. In the originally filed Sequence Listing, SEQ ID NO: 1 corresponded to the 120 base pair, double stranded molecule depicted in Figure 1. However, in the subsequently filed Sequence Listing, SEQ ID NO: 1 is a 240 nucleotide molecule that appears to correspond to a recitation of

the double stranded molecule of Figure 1 as if it were a single stranded molecule (rather than the 120 base pair molecule provided in the original Sequence Listing). As there is no basis for such a 240 base pair single stranded molecule in the originally filed specification, SEQ ID NO: 1 of the substitute Sequence Listing constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action, and to provide a new Sequence Listing that complies with the requirements of 37 CFR 1.821 through 1.825.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, as discussed above, in the originally filed Sequence Listing, SEQ ID NO: 1 corresponded to the 120 base pair, double stranded molecule depicted in Figure 1. However, in the Sequence Listing filed in response to the Notice of April 16, 2002, SEQ ID NO: 1 is a 240 nucleotide molecule that appears to correspond to a recitation of the double stranded molecule of Figure 1 as if it were a single stranded molecule (rather than the 120 base pair molecule provided in the original Sequence Listing). As there is no basis for such a 240 base pair single stranded molecule in the originally filed specification, SEQ ID NO: 1 of the

substitute Sequence Listing constitutes new matter. As claims 1-8 encompass SEQ ID NO: 1, the claims now also contain new matter as a result of the entry of the substitute Sequence Listing.

It is noted that the entry of a new Sequence Listing depicting SEQ ID NO: 1 as originally filed will be sufficient to overcome both the new matter objection above and the instant rejection of claims 1-8.

Oath/Declaration

11. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it includes a claim for priority to PCT/BR01/00035 under 35 U.S.C. 120. As the instant application is a 371 of PCT/BR01/00035, a claim under 35 U.S.C. 120 to the PCT application is not proper. (It is noted that the declaration does properly indicate that the instant application was filed as an International application, and further that the foreign priority claim in the oath is proper).

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite because it is unclear as to whether the claims are drawn to a method for infection diagnosis, as recited in the preamble of claim 1, or to a method of separating and detecting amplification products, as recited in the final process step of the claim. It is unclear as to how separation and “detection by appropriate technique” actually result in diagnosis. Further, the term “appropriate technique” is indefinite, because it is unclear as to what types of techniques would be considered “appropriate” (appropriate for what? appropriate to whom?). Clarification is required.

Claims 1-3 are indefinite over the recitation of the phrase “detection...of the specific region of the DNA of the *Schistosoma* genus described in ID SEQ n.1” in claim 1. It is noted that the method steps recited in the claim require PCR amplification, but do not require, e.g., a step of hybridization with a probe consisting of SEQ ID NO: 1, or otherwise require actual detection of the presence of a molecule consisting of or comprising SEQ ID NO: 1. It is unclear as to whether this recitation in the preamble of claim 1 is intended to require the actual detection of SEQ ID NO: 1, or whether the recitation “the specific region....” is intended to refer to a region within SEQ ID NO: 1 that is detected (e.g., the region flanked by the primers employed in the method). Further, the recitation “the DNA of the *Schistosoma* genus described in ID SEQ n.1” is indefinite because the specification indicates that SEQ ID NO: 1 is a repeat sequence of a particular species, *S. mansoni* (see, e.g., the description of Figure 1, as well as step c) of claim 1). Additionally, the recitations “the DNA of the *Schistosoma* genus” and “the specific region” lack antecedent basis. Accordingly, the meaning of this phrase and the manner in which it limits the claims cannot be ascertained.

Claims 1-3 are indefinite over the recitation of the limitations “the sample to be examined” in claim 1, step (a) and “the DNA of *Schistosoma sp*” in claim 1, step (b) because there is insufficient antecedent basis for these limitations in the claims.

Claims 1-3 and 6-8 are indefinite over the recitation of the phrase “specific primers constructed from the original sequence of *S. mansoni* described in ID SEQ n.1” in claims 1 and 6. It is unclear from this language how the primers of the claims relate to SEQ ID NO: 1. For example, does this language require that the primers of the claims actually be prepared using SEQ ID NO: 1 (e.g., by fragmenting SEQ ID NO: 1, or by digesting SEQ ID NO: 1 into individual nucleotides from which primers are “constructed”), or do the claims require primers such as the preferred primers of SEQ IDS Nos 2 and 3 (i.e., molecules that are identical to 20 nucleotide subsequences of SEQ ID NO: 1 and which together specifically amplify a portion thereof)? Clarification is required.

Claims 1-3 and 6-8 are indefinite over the recitation of the limitation “the original sequence of *S. mansoni* described in ID SEQ n.1.” There is no antecedent basis for this language in the claims, and it is unclear as to whether this phrase is intended to simply refer to SEQ ID NO: 1, or whether “the original sequence” described in SEQ ID NO: 1 refers to, e.g., particular subsequence of SEQ ID NO: 1. Clarification is required.

Claim 2 is indefinite over the recitation of the limitation “the specific region of the DNA of *Schistosoma sp*” because there is insufficient antecedent basis for this limitation in the claims.

Claim 3 is indefinite over the recitation of the limitation “the amplified products of stage (d)” because there is insufficient antecedent basis for this limitation in the claims.

Claim 5 is indefinite over the recitation “Primer of claim 4” because claim 4 is drawn to an “Oligonucleotide primer,” rather than a “Primer.” It is unclear as to whether claim 5 is intended to be limited to an oligonucleotide primer, or whether the claim (given the absence of clear reference to the oligonucleotide primer of claim 4) may encompass other types of primers. Clarification is required.

Claims 6-8 are indefinite over the recitation “all the necessary reagents to carry out a PCR.” While this language indicates a requirement for the inclusion of each and every reagent that one would require to perform a PCR, page 8 of the specification states:

A basic kit includes all the reagents necessary for carrying out the PCR technique, namely: specific primers, nucleotides and appropriate buffer solution for the amplification by PCR. Optionally, the kit may contain the enzyme Taq polymerase in quantities sufficient for amplification, standard DNA to be used as positive control of the reaction, buffer solution of the sample to prepare the amplified material for electrophoresis and protocol and instructions manual for the user. (emphasis added)

Accordingly, the specification suggests that the language “all the necessary reagents to carry out a PCR” may actually only encompass a subset of reagents (primers, nucleotides and buffer) required for PCR, rather than “all the necessary reagents”. Thus, as it is unclear as to what is actually encompassed by the recitation “all the necessary reagents” (and as to what reagents must actually be present to meet the requirements of the claims), the claims are vague and indefinite.

Claims 7-8 are indefinite over the recitation of the limitation “the specific region of the DNA of *Schistosoma sp.*” because there is insufficient antecedent basis for this recitation in the claims.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamburger et al (American Journal of Tropical Medicine and Hygiene 59(6):872-876 [12/1998])(hereinafter referred to as “Hamburger et al-1”), as evidenced by Hamburger et al (Molecular and Biochemical Parasitology 44(1):73-80 [1991])(hereinafter referred to as Hamburger et al-2).

It is first noted that this rejection refers to SEQ ID NO: 1 as originally filed.

Please see the new matter rejection and objection above for further explanation.

Hamburger et al-1 disclose a PCR assay for diagnosing *S. mansoni* infection in snails (see entire reference). Hamburger et al-1 disclose that their primers were “designed, based on the 121-base pair (bp) highly repeated sequence of *S. mansoni*” taught by Hamburger et al-2 (see page 872, right column, and page 873, left column of Hamburger et al-1). The first 120 nucleotides of the 121-base pair repeated sequence of Hamburger et al-2 are 100% identical to the sequence depicted by Applicants in Figure 1 (see Figure 4 of Hamburger et al-2); accordingly, instant SEQ ID NO: 1 depicts

the repeated sequence of Hamburger et al-2, with the exception of the final nucleotide. The Hamburger et al-2 reference establishes that it is an inherent property of the primers of Hamburger et al-1 that those primers were "constructed from the original sequence of *S. mansoni* described in" instant SEQ ID NO: 1, and that Hamburger et al-1's method detects "the specific region of the DNA of the *Schistosoma* genus described in" instant SEQ ID NO: 1. Hamburger et al-1 disclose steps of collecting biological samples (see page 873, left column), extracting *Schistosoma sp.* DNA from the samples (p. 873, left column), amplifying the repeated sequence with the disclosed primers (p. 873, left column), separating amplification products by electrophoresis (p. 873, left column, and Figures 2-3), and detecting products by staining (p. 873, left column and Figures 2-3). Accordingly, Hamburger et al-1 disclose each of steps (a)-(d) of the claimed method. Regarding claims 2 and 4, it is further noted that, like SEQ ID Nos 2 and 3, the primers of Hamburger et al-1 amplify and detect the repeat sequence described by Applicants as SEQ ID NO: 1; accordingly, the primers of Hamburger et al-1 both comprise and consist of sequences that are functionally equivalent to SEQ ID Nos 2 and 3, and that are "capable of amplifying the specific region of the DNA of *Schistosoma sp.*" Accordingly, Hamburger et al-1 anticipate the claimed invention.

16. Claims 4-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hamburger et al-2.

Hamburger et al-2 disclose a denatured, 120 base pair nucleic acid fragment having the repeat sequence depicted in Figure 4 (see entire reference, particularly Figure 4, as well as page 75, left column, and page 76, right column). It is an inherent

property of one strand of the fragment taught by Hamburger et al-2 (specifically, the strand depicted in Figure 4) that it is a primer comprising instant SEQ ID NO: 2, and of the other strand of the fragment taught by Hamburger et al-2 (specifically, the complement of the sequence depicted in Figure 4) that it is a primer comprising instant SEQ ID NO: 3. Particularly, it is noted that each of the molecules disclosed by Hamburger et al-2 could be readily employed as primers in a method such as primer extension.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamburger et al-1 in view of MacCallum (pages 99-103 of "Chapter 11: Detection of

PCR Amplified Products," *PCR Essential Data*, C.R. Newton, ed., John Wiley & Sons, Chichester, 1995), as evidenced by Hamburger et al-2.

It is first noted that this rejection refers to SEQ ID NO: 1 as originally filed.

Please see the new matter rejection and objection above for further explanation.

Hamburger et al-1 disclose a PCR assay for diagnosing *S. mansoni* infection in snails (see entire reference). Hamburger et al-1 disclose that their primers were "designed, based on the 121-base pair (bp) highly repeated sequence of *S. mansoni*" taught by Hamburger et al-2 (see page 872, right column, and page 873, left column of Hamburger et al-1). The first 120 nucleotides of the 121-base pair repeated sequence of Hamburger et al-2 are 100% identical to the sequence depicted by Applicants in Figure 1 (see Figure 4 of Hamburger et al-2); accordingly, instant SEQ ID NO: 1 depicts the repeated sequence of Hamburger et al-2, with the exception of the final nucleotide. The Hamburger et al-2 reference establishes that it is a property of the primers of Hamburger et al-1 that those primers were "constructed from the original sequence of *S. mansoni* described in" instant SEQ ID NO: 1, and that Hamburger et al-1's method detects "the specific region of the DNA of the *Schistosoma* genus described in" instant SEQ ID NO: 1. Hamburger et al-1 disclose steps of collecting biological samples (see page 873, left column), extracting *Schistosoma sp.* DNA from the samples (p. 873, left column), amplifying the repeated sequence with the disclosed primers (p. 873, left column), separating amplification products by electrophoresis (p. 873, left column, and Figures 2-3), and detecting products by staining (p. 873, left column and Figures 2-3). However, Hamburger et al-1 disclose the use of agarose gel electrophoresis and

ethidium bromide staining, rather than polyacrylamide gel electrophoresis and silver staining. MacCallum discloses that polyacrylamide gel electrophoresis combined with silver staining provides more sensitive detection than gel electrophoresis and ethidium bromide staining and, in contrast to ethidium bromide staining, "provides a permanent record of detection" (see pages 102-103, left column). Accordingly, in view of the teachings of MacCallum, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hamburger et al-1 so as to have separated amplification products by polyacrylamide gel electrophoresis and so as to have stained the resulting gel by silver staining, rather than with ethidium bromide. An ordinary artisan would have been motivated to have made such a modification for the advantage of increased sensitivity of detection and for the advantage of providing a permanent record of detection, as taught by MacCallum.

20. Claims 6-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Hamburger et al-1 in view of Ahern, as evidenced by Hamburger et al-2.

It is first noted that this rejection refers to SEQ ID NO: 1 as originally filed. Please see the new matter rejection and objection above for further explanation.

Hamburger et al-1 disclose a PCR assay for diagnosing *S. mansoni* infection in snails (see entire reference). Hamburger et al-1 disclose that their primers were "designed, based on the 121-base pair (bp) highly repeated sequence of *S. mansoni*" taught by Hamburger et al-2 (see page 872, right column, and page 873, left column of Hamburger et al-1). The first 120 nucleotides of the 121-base pair repeated sequence of Hamburger et al-2 are 100% identical to the sequence depicted by Applicants in

Figure 1 (see Figure 4 of Hamburger et al-2); accordingly, instant SEQ ID NO: 1 depicts the repeated sequence of Hamburger et al-2, with the exception of the final nucleotide. The Hamburger et al-2 reference establishes that it is a property of the primers of Hamburger et al-1 that those primers were “constructed from the original sequence of *S. mansoni* described in” instant SEQ ID NO: 1. Further, regarding claim 7, it is noted that, like SEQ ID Nos 2 and 3, the primers of Hamburger et al-1 amplify and detect the repeat sequence described by Applicants as SEQ ID NO: 1; accordingly, the primers of Hamburger et al-1 consist of sequences that are functionally equivalent to SEQ ID Nos 2 and 3, and that are “capable of amplifying the specific region of the DNA of *Schistosoma sp.*” Hamburger et al-1 do not teach packaging the reagents employed in their methods into kits, or teach kits including “a protocol and an instruction manual,” as required by the claims. Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money (see p. 3/5-4/5). Ahern specifically teaches kits that supply “all of the necessary reagents for a particular research application,” as well as “detailed instructions to follow” (page 4/5). In view of the teachings of Ahern, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Hamburger et al-1 so as to have packaged all of the reagents employed in Hamburger et al-1’s PCR assay into a kit, and further to have included instructions in any well-known form or forms (manual form, card form, etc.) in said kit. An ordinary artisan would have been motivated to have made such a modification in order to have provided all the reagents needed to perform Hamburger et al-1’s PCR assay, as well as the necessary

instructions to properly perform the assay, to practitioners in a convenient format, for the advantages of efficiency and cost-effectiveness.

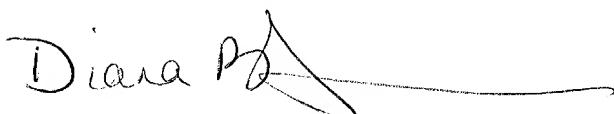
Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hamburger et al (Am. J. Trop. Med. Hyg. 59(3):468-473 [1998]) disclose a PCR assay for detection of *S. mansoni* in water samples that comprises amplification of the 121-base pair repeated sequence disclosed by Hamburger et al-2 (see entire reference, particularly Figure 1).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.



Diana B. Johannsen
September 3, 2003